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Attorney Docket No. 10142/03601 (03-225)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s)	:	DiMatteo et al.
Serial No.	:	10/762,715
Filed	:	January 22, 2004
For	:	Valved Catheter to Bypass Connector
Group Art Unit	:	3767
Confirmation No.	:	5203
Examiner	:	Phillip A. Gray

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By: Oleg F. Kaplun, Reg. No. 45,559 Date: August 15, 2008

TRANSMITTAL

In response to the Notifications of Non-Compliant Appeal Brief mailed on July 30, 2008 and August 1, 2008, transmitted herewith please find a revised Appeal Brief for filing in the above-identified application. No fees are believed to be required. However, the Commissioner is hereby authorized to charge the **Deposit Account of Fay Kaplun & Marcin, LLP NO. 50-1492** for any additional required fees. A copy of this paper is enclosed for that purpose.

Respectfully submitted,

Dated: August 15, 2008

By: _____
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PATENT
Attorney Docket No.: 10142/03601

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	)	
	)	
DiMatteo et al.	)	
	)	
Serial No.: 10/762,715	)	Group Art Unit: 3767
	)	
Filed: January 22, 2004	)	Examiner: Phillip Gray
	)	
For: VALVED CATHETER TO BYPASS CONNECTOR	)	**Board of Patent Appeals and Interferences**
	)	

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APPEAL BRIEF UNDER 37 C.F.R. § 41.37

In support of the Notice of Appeal filed June 18, 2008, and pursuant to 37 C.F.R. § 41.37, Appellants present their Appeal Brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 1 - 5, 7 - 19, and 21 - 24 in the Final Office Action dated March 21, 2008. The appealed claims are set forth in the attached Claims Appendix.

1. Real Party in Interest

This application is assigned to NAMIC/VA, Inc., the real party in interest.

2. Related Appeals and Interferences

An initial Appeal Brief in connection with the present application was filed on June 1, 2007. The application was subsequently reopened for examination and a Non-Final Office Action issued on September 24, 2007.

3. Status of the Claims

Claims 1 - 5, 7 - 19, and 21 - 24 stand rejected in the Final Office Action. Claims 6 and 20 have been cancelled. The final rejection of claims 1 - 5, 7 - 19, and 21 - 24 is being appealed.

4. Status of Amendments

All amendments submitted by the Appellants have been entered.

5. Summary of Claimed Subject Matter

The present invention describes, as recited in independent claim 1, a connector for injecting fluid to a catheter. The connector 100 comprises an attachment portion 104 adapted to fluidly couple to a source of pressurized fluid. (*See* Specification, p. 6, ll. 14 - 28; Fig. 1). The connector comprises a bypass element (*e.g.*, 108) fluidly connected to the attachment portion. (*See Id.*, p. 7, l. 1 - p. 8, l. 3; Figs. 1-2). The bypass element is adapted to open a valve of the catheter to permit fluid to flow into the catheter without impinging on the valve. (*See Id.*). The

connector comprises an overpressure control element (*e.g.*, 306) adapted to maintain a pressure of fluid within the connector below a predetermined threshold level. (*See Id.*, p. 9, ll. 7 - 16; Fig. 1).

The present invention describes, as recited in independent claim 18, a fluid coupler 100. The fluid coupler 100 comprises an elongated tube 102 extending between a first end 104 adapted for fluid connection to a power injector and a second end adapted for fluid connection (via extensions 106) to a catheter 200 including a valve 202 in a proximal part thereof. (*See Id.*, p. 6, ll. 14 - 28; p. 7, l. 22 - p. 8, l. 3; Figs. 1 - 2). The second end is insertable into the catheter beyond the valve thereof so that fluid passes through the fluid coupler into the catheter to a distal end thereof without passing through the valve. (*See Id.*). The fluid coupler comprises a pressure control element (306) adapted to limit a fluid pressure within the fluid coupler to a predetermined threshold level. (*See Id.*, p. 9, ll. 7 - 16; Fig. 1).

6. Grounds of Rejection to be Reviewed on Appeal

I. Whether claims 1 - 5, 7 - 8, 11 - 13, 18 - 19, 21 and 23 are unpatentable under 35 U.S.C. § 102(b), or alternatively, under 35 U.S.C. § 103(a) over U.S. Pat. No. 5,125,893 to Dryden.

II. Whether claims 9 - 10, 22 and 24 are unpatentable under 35 U.S.C. § 103(a) over Dryden in view of U.S. Pat. No. 6,375,637 to Campbell et al. ("Campbell").

III. Whether claims 14 - 17 are unpatentable under 35 U.S.C. § 103(a) over Dryden.

7. Argument

I. The Rejection of Claims 1 - 5, 7 - 8, 11 - 13, 18 - 19, 21 and 23 Under 35 U.S.C. § 102(b), or Alternatively, Under 35 U.S.C. § 103(a) as Unpatentable Over Dryden Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 1 - 5, 7 - 8, 11 - 13, 18 - 19, 21 and 23 were rejected under 35 U.S.C. 102(b), or alternatively, under 35 U.S.C. § 103(a) as unpatentable over Dryden. (*See* 3/21/08 Office Action, pp. 4 - 5). The Examiner has indicated that the valve 35 of Dryden functions as an overpressure control element therein. The Examiner has further indicated that the recitation of the term "adapted to" is not a positive limitation and only requires the ability to so perform. (*See* 3/21/08 Final Office Action, p. 3).

B. Dryden Fails to Teach or Suggest An Overpressure Control Element Adapted to Maintain a Pressure of Fluid Within the Connector Below a Predetermined Threshold Level, as Recited in Claim 1

It is respectfully submitted that the recitation of an "overpressure control element adapted to maintain a pressure of fluid within the connector below a predetermined threshold level" is indeed a structural limitation of the connector of claim 1. Specifically, claim 1 explicitly indicates that the overpressure control element must be structured so that flow therethrough can not exceed a desired maximum pressure. Those skilled in the art will understand that this behavior is dictated by the structure of the element and is not simply a statement of an intended

use or purpose for the device. There are many elements which would be structurally unsuitable for use as the recited overpressure control element (e.g., elements having substantially large lumens extending therethrough). It is therefore noted that the limitation of an "overpressure control element adapted to maintain a pressure of fluid within the connector below a predetermined threshold level" is a structural limitation.

Still further, it is noted that the term "overpressure control element" is itself a structural limitation indicative of an element for controlling a pressure of the controller to prevent an overpressure therein. Specifically, the plain meaning of the term "overpressure control element" is structural – i.e., an element included in the device to prevent an overpressure state in the controller. (*See* MPEP, § 2111.01). Accordingly, even if the "adapted to" limitation were to be removed from claim 1, the "overpressure control element" limitation alone would still be a sufficient structural limitation to overcome Dryden, as will be described in greater detail below. It is therefore respectfully submitted that the limitation of an "overpressure control element adapted to maintain a pressure of fluid within the connector below a predetermined threshold level" is a structural limitation.

Furthermore, it is respectfully submitted that the valve 35 of Dryden does not meet the limitations of the overpressure control element recited in claim 1. Specifically, the valve 35 of Dryden is described only as controlling an amount of irrigation fluid supplied to the catheter 28. Dryden makes absolutely no mention of any control of the pressure in the catheter 28, much less by the valve 35 which is described only as having a simple on/off functionality. (*See* Dryden, col.

2, ll. 55 - 56). Dryden neither shows nor suggests any valve for maintaining a pressure within a connector below a threshold level as recited in claim 1. Additionally, such a function would not be of any use in regard to the small amounts of irrigation fluids supplied by the Dryden device. It is respectfully submitted that the Examiner's statements regarding this functionality of the valve 35 are purely speculative and in no way supported by the disclosure of Dryden.

The Examiner has asserted that it would have been obvious to have constructed the valve 35 as a pressure control element as claimed. (*See* 3/21/08 Office Action, p. 4). However, it is respectfully submitted that, as described above, Dryden provides no motivation to modify its device to include "an overpressure control element," as recited in claim 1. Specifically, as the relevant portions of the Dryden device (i.e., the irrigation fluid supply apparatus including the source 12, the valve 35 and the lumen 29) are directed solely to low pressure applications, it is submitted that those skilled in the art would not have found any motivation to modify the on/off valve 35 to enable it to perform an overpressure control function as recited in claim 1.

Thus, it is respectfully submitted that obviousness can not be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is no teaching, suggestion, or motivation to do so and that this represents an impermissible hindsight reconstruction of the invention. (*See* In re Kahn, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006)).

It is therefore respectfully submitted that Dryden fails to show or suggest a connector for injecting fluid to a catheter comprising "*an overpressure control element adapted to maintain a*

pressure of fluid within the connector below a predetermined threshold level," as recited in claim 1 and that claim 1 is allowable over Dryden. Because claims 2 - 5, 7 - 8 and 11 - 13 depend from and, therefore, include the limitations of claim 1, it is respectfully submitted that these claims are allowable for at least the reasons stated above.

Independent claim 18 includes limitations substantially similar to those of claim 1 discussed above. Specifically, claim 18 recites "an elongated tube extending between a first end adapted for fluid connection to a power injector and a second end adapted for fluid connection to a catheter including a valve in a proximal part thereof, the second end being insertable into the catheter beyond the valve thereof so that fluid passes through the fluid coupler into the catheter to a distal end thereof without passing through the valve and a *pressure control element adapted to limit a fluid pressure within the coupler to a predetermined threshold level*." Applicants respectfully submit that claim 18 is allowable over Dryden for the same reasons noted above in regard to claim 1. Because claims 19, 21 and 23 depend from and, therefore, include the limitations of claim 18, it is respectfully submitted that these claims are allowable for at least the reasons stated above.

II. The Rejection of Claims 9 - 10, 22 and 24 Under 35 U.S.C. § 103(a) as Unpatentable Over Dryden in view of Campbell Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 9 - 10, 22 and 24 were rejected under 35 U.S.C. 103(a) as unpatentable over Dryden in view of Campbell. (*See* 3/21/08 Office Action, p. 6).

B. Dryden Fails to Teach or Suggest An Overpressure Control Element Adapted to Maintain a Pressure of Fluid Within the Connector Below a Predetermined Threshold Level, as Recited in Claim 1

As stated above in regard to claim 1 from which claim 9 - 10 depend, Dryden fails to teach or suggest the limitations of claim 1. The Campbell device is directed to a catheter balloon having a controlled failure mechanism therein. (*See* Campbell, col. 4, ll. 55 - 58). The Campbell device fails to overcome the deficiencies of the Dryden device, particularly "an overpressure control element adapted to maintain a pressure of fluid within the connector below a predetermined threshold level," as recited in claim 1. It is therefore submitted that Dryden and Campbell, either alone or in combination, fail to teach or suggest the limitations of claim 1. Because claims 9 and 10 depend from and therefore include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Claim 18 recites limitations substantially similar to claim 1, including "an elongated tube extending between a first end adapted for fluid connection to a power injector and a second end adapted for fluid connection to a catheter including a valve in a proximal part thereof, the second end being insertable into the catheter beyond the valve thereof so that fluid passes through the fluid coupler into the catheter to a distal end thereof without passing through the valve and a *pressure control element adapted to limit a fluid pressure within the coupler to a predetermined threshold level.*" It is respectfully submitted that Dryden and Campbell, either alone or in combination, fail to teach or suggest the limitations of claim 18. Because claims 22 and 24 depend from and therefore include all of the limitations of claim 18, it is respectfully submitted

that these claims are also allowable.

III. The Rejection of Claims 14 - 17 Under 35 U.S.C. § 103(a) as Unpatentable Over Dryden Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 14 - 17 were rejected under 35 U.S.C. 103(a) as unpatentable over Dryden. (*See* 3/21/08 Office Action, p. 7).

B. Dryden Fails to Teach or Suggest An Overpressure Control Element Adapted to Maintain a Pressure of Fluid Within the Connector Below a Predetermined Threshold Level, as Recited in Claim 1.

Claims 14 - 17 depend from, and therefore include all of the limitations of claim 1. As noted above, Dryden fails to teach or suggest the limitations of claim 1. Thus, it is respectfully submitted that claims 14 - 17 are allowable for at least the same reasons stated above in regard to claim 1. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection of claim 14 - 17.

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8. Conclusion

For the reasons set forth above, Appellants respectfully request that the Board reverse the final rejections of the claims by the Examiner under 35 U.S.C.§ 103(a) and indicate that claims 1 - 5, 7 - 19, and 21 - 24 are allowable.

Respectfully submitted,

Date: August 15, 2008

By:_____
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CLAIMS APPENDIX

1. (Previously Presented) A connector for injecting fluid to a catheter, comprising:

an attachment portion adapted to fluidly couple to a source of pressurized fluid;

a bypass element fluidly connected to the attachment portion, the bypass element being adapted to open a valve of the catheter to permit fluid to flow into the catheter without impinging on the valve; and

an overpressure control element adapted to maintain a pressure of fluid within the connector below a predetermined threshold level.

2. (Previously Presented) The connector according to claim 1, wherein the bypass element comprises an elongated tubular component insertable into the catheter through the valve of the catheter.

3. (Original) The connector according to claim 2, wherein the elongated tubular component has a diameter selected to fit in a flow opening of the valve of the catheter.

4. (Original) The connector according to claim 2, wherein the elongated tubular component is hypotube.

5. (Original) The connector according to claim 2, wherein the elongated tubular component includes an outlet which, when the elongated tubular component is inserted into the catheter through the valve, is located distally of the valve.

6. (Canceled)

7. (Original) The connector according to claim 1, wherein the overpressure control element comprises a pressure relief valve.

8. (Original) The connector according to claim 1, wherein the overpressure control element comprises a controlled failure element designed to fail when a fluid pressure therein reaches the threshold level.

9. (Original) The connector according to claim 8, wherein the controlled failure element is an extension tube.

10. (Original) The connector according to claim 1, further comprising an external collection jacket disposed around the overpressure control element.

11. (Original) The connector according to claim 1, wherein the bypass element is adapted to open a pressure actuated safety valve of a venous catheter.

12. (Original) The connector according to claim 1, wherein the attachment portion is adapted to connect to a contrast media power injection system.

13. (Original) The connector according to claim 1, wherein the threshold level is selected to be less than a burst pressure of a catheter with which the connector is to be used.

14. (Original) The connector according to claim 13, wherein the threshold level is approximately 300 psi.

15. (Original) The connector according to claim 14, wherein the threshold level is approximately 100 psi.

16. (Original) The connector according to claim 13, wherein the threshold level is approximately 80 psi.

17. (Original) The connector according to claim 16, wherein the threshold level is approximately 40 psi.

18. (Previously Presented) A fluid coupler comprising:

an elongated tube extending between a first end adapted for fluid connection to a power injector and a second end adapted for fluid connection to a catheter including a valve in a proximal part thereof, the second end being insertable into the catheter beyond the valve thereof so that fluid passes through the fluid coupler into the catheter to a distal end thereof without passing through the valve; and

a pressure control element adapted to limit a fluid pressure within the coupler to a predetermined threshold level.

19. (Original) The coupler according to claim 18, wherein the elongated tube is a hypotube.

20. (Canceled)

21. (Original) The coupler according to claim 18, wherein the pressure control element comprises a section having a burst pressure lower than a burst pressure of the catheter.

22. (Original) The coupler according to claim 18, wherein the pressure control element comprises an extension tube connected to the first end.

23. (Original) The coupler according to claim 18, wherein the pressure control element comprises a pressure relief valve.

24. (Original) The coupler according to claim 18, further comprising a fluid collection jacket surrounding the pressure control element.

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EVIDENCE APPENDIX

No evidence has been entered or relied upon in the present appeal.

RELATED PROCEEDING APPENDIX

No decisions have been rendered regarding the present appeal or any proceedings related thereto.